SENATE BILL No. 275

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-7.4; IC 27-8-14.3; IC 27-13-7-15.5.

Synopsis: Clinical trials. Defines "associated treatment cost" for purposes of payment for medically necessary treatment and drugs and devices associated with clinical trial treatments. Requires group health benefit plans for public employees, individual and group accident and sickness insurance policies, and individual and group health maintenance organization contracts to provide coverage for associated treatment cost. Prohibits dollar limits, deductibles, copayments, or coinsurance requirements on coverage of associated treatment cost that are less favorable than those for physical illness generally. Requires health benefit plan administrators, insurers, and health maintenance organizations to submit annual reports to the insurance commissioner describing clinical trials for which associated treatment cost was covered. Requires the insurance commissioner to compile information gathered and make an annual report available to the public. Establishes a work group on health care coverage for associated treatment cost to study and make recommendations regarding costs and benefits of the coverage required under this act.

Effective: July 1, 2001.

Gard

January 11, 2001, read first time and referred to Committee on Health and Provider Services.



2001

First Regular Session 112th General Assembly (2001)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in this style type, and deletions will appear in this style type.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or *this style type* reconciles conflicts between statutes enacted by the 2000 General Assembly.

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SENATE BILL No. 275

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

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4	means:
3	1, 2001]: Sec. 7.4. (a) As used in this chapter, "administrator"
2	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
1	SECTION 1. IC 5-10-8-7.4 IS ADDED TO THE INDIANA CODE

- (1) the state personnel department;
- (2) an entity with which the state contracts to administer health coverage under section 7(b) of this chapter; or
- (3) a prepaid health care delivery plan with which the state contracts under section 7(c) of this chapter.
- (b) As used in this section, "associated treatment cost" means the cost of a medically necessary treatment associated with clinical trial treatment. The term does not include:
 - (1) the cost of an investigational drug or device used as part of the clinical trial treatment;
 - (2) the cost of nonhealth care services associated with the clinical trial treatment;
 - (3) the cost of managing the research associated with the



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1	clinical trial treatment; or
2	(4) a cost not covered under the health benefit plan for
3	noninvestigational treatments.
4	(c) As used in this section, "clinical trial treatment" means:
5	(1) treatment provided in a phase II, phase III, or phase IV
6	clinical trial for a life threatening condition;
7	(2) prevention studies in a phase I, phase II, phase III, or
8	phase IV clinical trial for cancer;
9	(3) early detection studies in a phase I, phase II, phase III, or
10	phase IV clinical trial for cancer; or
11	(4) treatment studies in a phase I, phase II, phase III, or phase
12	IV clinical trial for cancer;
13	that is approved by the National Institutes of Health or one (1) of
14	its cooperative groups or centers, the federal Food and Drug
15	Administration in the form of an investigational new drug
16	application, the United States Department of Veterans Affairs, or
17	an institutional review board of an institution in Indiana that has
18	a multiple project assurance contract approved by the office of
19	protection from research risks of the National Institutes of Health.
20	(d) As used in this section, "cooperative group" means a formal
21	network of facilities that collaborate on research projects and have
22	an established peer review program operating within the group
23	that is approved by the National Institutes of Health. The term
24	includes:
25	(1) the National Cancer Institute Clinical Cooperative Group;
26	(2) the National Cancer Institute Community Clinical
27	Oncology Program;
28	(3) the AIDS Clinical Trials Group; and
29	(4) the Community Programs for Clinical Research in AIDS.
30	(e) As used in this section, "covered individual" means an
31	individual who is:
32	(1) covered under a self-insurance program established under
33	section 7(b) of this chapter to provide group health coverage;
34	or
35	(2) entitled to services under a contract for health services
36	entered into or renewed under section 7(c) of this chapter.
37	(f) As used in this chapter, "health benefit plan" means:
38	(1) a self-insurance program established under section 7(b) of
39	this chapter to provide group health coverage; or
40	(2) a contract for health services entered into or renewed
41	under section 7(c) of this chapter.
42	(g) As used in this section, "multiple project assurance



1	contract" means a contract between an institution and the United
2	States Department of Health and Human Services that defines the
3	relationship between the institution and the United States
4	Department of Health and Human Services and specifies the
5	responsibilities of the institution and procedures that will be used
6	by the institution to protect human research subjects.
7	(h) A health benefit plan must provide a covered individual with
8	coverage for associated treatment cost if:
9	(1) the facility and personnel providing the clinical trial
10	treatment are approved by the organization sponsoring the
11	clinical trial protocol and the institutional review board of the
12	institution providing the clinical trial treatment;
13	(2) there is no clearly superior, noninvestigational treatment
14	alternative to the clinical trial treatment; and
15	(3) the available clinical or preclinical data provide a
16	reasonable expectation that the clinical trial treatment will be
17	at least as effective as a noninvestigational alternative.
18	(i) The coverage required under subsection (h) includes
19	associated treatment cost for a drug or device approved for sale by
20	the federal Food and Drug Administration to the extent that the
21	manufacturer, distributor, or provider of the drug or device does
22	not pay the cost, regardless of whether the drug or device is
23	approved for the covered individual's particular condition.
24	(j) The coverage required under subsections (h) and (i) may not
25	be subject to dollar limits, deductibles, copayments, or coinsurance
26	provisions that are less favorable to a covered individual than the
27	dollar limits, deductibles, copayments, or coinsurance provisions
28	applying to physical illness generally under the health benefit plan.
29	(k) On or before June 1 of each year, each administrator shall
30	submit to the insurance commissioner, on a form approved by the
31	insurance commissioner, a report describing clinical trials for
32	which the health benefit plan covered associated treatment cost
33	during the prior year.
34	(l) The insurance commissioner shall compile an annual
35	summary report of the information submitted under subsection (k)
36	and make copies available to the public.
37	(m) The insurance commissioner shall adopt rules under
38	IC 4-22-2 to implement subsections (k) and (l).
39	SECTION 2. IC 27-8-14.3 IS ADDED TO THE INDIANA CODE
40	AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE

Chapter 14.3. Coverage Associated With Clinical Trials



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JULY 1, 2001]:

1	Sec. 1. (a) As used in this chapter, "accident and sickness
2	insurance policy" means an insurance policy that:
3	(1) provides one (1) or more of the types of insurance
4	described in IC 27-1-5-1, classes 1(b) and 2(a); and
5	(2) is issued on an individual or group basis.
6	(b) As used in this chapter, "associated treatment cost" means
7	the cost of a medically necessary treatment associated with clinical
8	trial treatment. The term does not include:
9	(1) the cost of an investigational drug or device used as part
0	of the clinical trial treatment;
1	(2) the cost of nonhealth care services associated with the
2	clinical trial treatment;
.3	(3) the cost of managing the research associated with the
4	clinical trial treatment; or
.5	(4) a cost not covered under the accident and sickness
.6	insurance policy for noninvestigational treatments.
.7	(c) As used in this chapter, "clinical trial treatment" means:
.8	(1) treatment provided in a phase II, phase III, or phase IV
9	clinical trial for a life threatening condition;
20	(2) prevention studies in a phase I, phase II, phase III, or
21	phase IV clinical trial for cancer;
22	(3) early detection studies in a phase I, phase II, phase III, or
23	phase IV clinical trial for cancer; or
24	(4) treatment studies in a phase I, phase II, phase III, or phase
25	IV clinical trial for cancer;
26	that is approved by the National Institutes of Health or one (1) of
27	its cooperative groups or centers, the federal Food and Drug
28	Administration in the form of an investigational new drug
29	application, the United States Department of Veterans Affairs, or
30	an institutional review board of an institution in Indiana that has
31	a multiple project assurance contract approved by the office of
32	protection from research risks of the National Institutes of Health.
33	(d) As used in this chapter, "cooperative group" means a formal
34	network of facilities that collaborate on research projects and have
35	an established peer review program operating within the group
36	that is approved by the National Institutes of Health. The term
37	includes:
88	(1) the National Cancer Institute Clinical Cooperative Group;
39 10	(2) the National Cancer Institute Community Clinical
10 11	Oncology Program; (3) the Aids Clinical Trials Crowns and
11	(3) the Aids Clinical Trials Group; and
12	(4) the community programs for clinical research in AIDS.



1	(e) As used in this chapter, "insured" means an individual who
2	is entitled to coverage under an accident and sickness insurance
3	policy that the insurer issues in Indiana.
4	(f) As used in this chapter, "multiple project assurance
5	contract" means a contract between an institution and the United
6	States Department of Health and Human Services that defines the
7	relationship between the institution and the United States
8	Department of Health and Human Services and specifies the
9	responsibilities of the institution and procedures that will be used
10	by the institution to protect human research subjects.
11	Sec. 2. (a) An insurer must provide coverage for associated
12	treatment cost in an accident and sickness insurance policy that the
13	insurer issues in Indiana if:
14	(1) the facility and personnel providing the clinical trial
15	treatment are approved by the organization sponsoring the
16	clinical trial protocol and the institutional review board of the
17	institution providing the clinical trial treatment;
18	(2) there is no clearly superior, noninvestigational treatment
19	alternative to the clinical trial treatment; and
20	(3) the available clinical or preclinical data provide a
21	reasonable expectation that the clinical trial treatment will be
22	at least as effective as a noninvestigational alternative.
23	(b) The coverage required under subsection (a) includes
24	associated treatment cost for a drug or device approved for sale by
25	the federal Food and Drug Administration to the extent that the
26	manufacturer, distributor, or provider of the drug or device does
27	not pay the cost, regardless of whether the drug or device is
28	approved for the insured's particular condition.
29	(c) The coverage required under this chapter may not be subject
30	to dollar limits, deductibles, or coinsurance provisions that are less
31	favorable to an insured than the dollar limits, deductibles, or
32	coinsurance provisions applying to physical illness generally under
33	the accident and sickness insurance policy.
34	Sec. 3. (a) On or before June 1 of each year, each insurer shall
35	submit to the commissioner, on a form approved by the
36	commissioner, a report describing clinical trials for which the
37	insurer covered associated treatment cost during the prior year.
38	(b) The commissioner shall compile an annual summary report
39	of the information submitted under subsection (a) and make copies
40	available to the public.
41	(c) The commissioner shall adopt rules under IC 4-22-2 to
42	implement this section.



1	SECTION 3. IC 27-13-7-15.5 IS ADDED TO THE INDIANA
2	CODE AS A NEW SECTION TO READ AS FOLLOWS
3	[EFFECTIVE JULY 1, 2001]: Sec. 15.5. (a) As used in this section,
4	"associated treatment cost" means the cost of a medically
5	necessary treatment associated with clinical trial treatment. The
6	term does not include:
7	(1) the cost of an investigational drug or device used as part
8	of the clinical trial treatment;
9	(2) the cost of nonhealth care services associated with the
10	clinical trial treatment;
11	(3) the cost of managing the research associated with the
12	clinical trial treatment; or
13	(4) a cost not covered under the health maintenance
14	organization contract for noninvestigational treatments.
15	(b) As used in this section, "clinical trial treatment" means:
16	(1) treatment provided in a phase II, phase III, or phase IV
17	clinical trial for a life threatening condition;
18	(2) prevention studies in a phase I, phase II, phase III, or
19	phase IV clinical trial for cancer;
20	(3) early detection studies in a phase I, phase II, phase III, or
21	phase IV clinical trial for cancer; or
22	(4) treatment studies in a phase I, phase II, phase III, or phase
23	IV clinical trial for cancer;
24	that is approved by the National Institutes of Health or one (1) of
25	its cooperative groups or centers, the federal Food and Drug
26	Administration in the form of an investigational new drug
27	application, the United States Department of Veterans Affairs, or
28	an institutional review board of an institution in Indiana that has
29	a multiple project assurance contract approved by the office of
30	protection from research risks of the National Institutes of Health.
31	(c) As used in this section, "cooperative group" means a formal
32	network of facilities that collaborate on research projects and have
33	an established peer review program operating within the group
34	that is approved by the National Institutes of Health. The term
35	includes:
36	(1) the National Cancer Institute Clinical Cooperative Group;
37	(2) the National Cancer Institute Community Clinical
38	Oncology Program;
39	(3) the AIDS Clinical Trials Group; and
40	(4) the community programs for clinical research in AIDS.
41	(d) As used in this section, "multiple project assurance
42	contract" means a contract between an institution and the United



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1	States Department of Health and Human Services that defines the
2	relationship between the institution and the United States
3	Department of Health and Human Services and specifies the
4	responsibilities of the institution and procedures that will be used
5	by the institution to protect human research subjects.
6	(e) A health maintenance organization issued a certificate of
7	authority in Indiana shall provide coverage for associated
8	treatment cost under an individual or group contract that provides
9	coverage for basic health care services if:
10	(1) the facility and personnel providing the clinical trial
11	treatment are approved by the organization sponsoring the
12	clinical trial protocol and the institutional review board of the
13	institution providing the clinical trial treatment;
14	(2) there is no clearly superior, noninvestigational treatment
15	alternative to the clinical trial treatment; and
16	(3) the available clinical or preclinical data provide a
17	reasonable expectation that the clinical trial treatment will be
18	at least as effective as a noninvestigational alternative.
19	(f) The coverage required under subsection (e) includes
20	associated treatment cost for a drug or device approved for sale by
21	the federal Food and Drug Administration to the extent that the
22	manufacturer, distributor or provider of the drug or device does
23	not pay the cost, regardless of whether the drug or device is
24	approved for the enrollee's particular condition.
25	(g) The coverage required by subsections (e) and (f) may not be
26	subject to dollar limits, deductibles, copayments, or coinsurance
27	provisions that are less favorable to an enrollee than the dollar

- (g) The coverage required by subsections (e) and (f) may not be subject to dollar limits, deductibles, copayments, or coinsurance provisions that are less favorable to an enrollee than the dollar limits, deductibles, copayments, or coinsurance provisions applying to physical illness generally under the health maintenance organization contract.
- (h) On or before June 1 of each year, each health maintenance organization shall submit to the commissioner, on a form approved by the commissioner, a report describing clinical trials for which the health maintenance organization covered associated treatment cost during the prior year.
- (i) The commissioner shall compile an annual summary report of the information gathered under subsection (h) and make copies available to the public.
- (j) The commissioner shall adopt rules under IC 4-22-2 to implement subsections (h) and (i).

SECTION 4. [EFFECTIVE JULY 1, 2001] (a) The work group on health care coverage for associated treatment cost is created to



1	assess the costs and benefits of health care coverage by:
2	(1) state employee health benefit plans under IC 5-10-8-7.4, as
3	added by this act;
4	(2) insurers under IC 27-8-14.3, as added by this act; and
5	(3) health maintenance organizations under IC 27-13-7-15.5,
6	as added by this act;
7	for associated treatment cost as defined in IC 5-10-8-7.4,
8	IC 27-8-14.3-1, and IC 27-13-7-15.5, all as added by this act.
9	(b) The work group on health care coverage for associated
10	treatment cost consists of nine (9) members appointed by the
11	insurance commissioner before January 1, 2002, as follows:
12	(1) One (1) member from the Indiana University School of
13	Medicine.
14	(2) One (1) member from the Indiana State Medical
15	Association.
16	(3) Two (2) representatives, including one (1) medical director
17	licensed to practice medicine in Indiana, from accident and
18	sickness insurers granted certificates of authority in Indiana.
19	(4) Two (2) representatives, including one (1) medical director
20	licensed to practice medicine in Indiana, from health
21	maintenance organizations granted certificates of authority in
22	Indiana.
23	(5) One (1) member from the state personnel department.
24	(6) One (1) member of the public.
25	(7) The insurance commissioner, or the commissioner's
26	designee.
27	(c) The insurance commissioner, or the commissioner's
28	designee, shall serve as chairperson.
29	(d) Members shall serve until the final report is submitted under
30	subsection (g).
31	(e) Each member of the work group who is not a state employee
32	is entitled to the minimum salary per diem provided by
33	IC 4-10-11-2.1(b). The member is also entitled to reimbursement
34	for traveling expenses and other expenses actually incurred in
35	connection with the member's duties, as provided in the state travel
36	policies and procedures established by the Indiana department of
37	administration and approved by the budget agency.
38	(f) The work group on health care coverage for associated
39	treatment cost for clinical trials shall:
40	(1) develop a methodology for assessing the economic and
41	clinical impact of the health care coverage required under
42	IC 5-10-8-7.4, IC 27-8-14.3, and IC 27-13-7-15.5, all as added



1	by this act, for associated treatment cost;	
2	(2) collect from health care providers and payers pertinent	
3		
4	aggregate clinical and financial data on insured treatments to assess differences in associated treatment cost and clinical	
5	outcomes between insureds treated in clinical trials and	
6	insureds treated outside clinical trials;	
7	(3) review any other issues the workgroup considers	
8	appropriate; and	
9	(4) make recommendations to the insurance commissioner	
.0	pertaining to coverage for associated treatment cost.	
.1	(g) The work group shall submit a final report, including	
2	findings and recommendations, to the legislative council on or	
.3	before June 30, 2003.	
4	(h) This SECTION expires June 30, 2006.	
.5	SECTION 5. [EFFECTIVE JULY 1, 2001] (a) IC 5-10-8-7.4, as	
.6	added by this act, applies to a self-insurance program or a contract	
.7	with a prepaid health care delivery plan established, entered into,	
.8	or renewed after June 30, 2001.	
9	(b) IC 27-8-14.3, as added by this act, applies to an accident and	
20	sickness insurance policy entered into, issued, delivered, or	
21	renewed after June 30, 2001.	
22	(c) IC 27-13-7-15.5, as added by this act, applies to a health	
23	maintenance organization contract entered into, issued, delivered,	
24	or renewed after June 30, 2001.	
25	(d) This SECTION expires June 30, 2007.	

